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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/678,591	10/03/2000	Steven C. Quay	20424-000510US	5933

7590 12/18/2001

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EXAMINER
JONES, DWAYNE C

ART UNIT	PAPER NUMBER
1614	7

DATE MAILED: 12/18/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/678,591	Applicant(s) Quay, S. C.
	Examiner Dwayne C. Jones	Art Unit 1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL.** 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)☐ All b)☐ Some* c)☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15)☒ Notice of References Cited (PTO-892)
16)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
18)☐ Interview Summary (PTO-413) Paper No(s). _____
19)☐ Notice of Informal Patent Application (PTO-152)
20)☐ Other:

DETAILED ACTION

Status of Claims

1. Claims 1-38 are pending.

2. Claims 1-38 are rejected.

Information Disclosure Statement

3. The information disclosure statement filed October 3, 2000 fails to comply with 37 CFR 1.98(a)(1), which requires a list of all patents, publications, or other information submitted for consideration by the Office. It has been placed in the application file, but the information referred to therein has not been considered.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1, 26 and 33 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of breast cancer, does not reasonably provide enablement for the prevention or prophylaxis of breast cancer. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims. The instant invention fails to provide support for the prevention or prophylaxis of breast cancer. The cancer therapy art

remains highly unpredictable, and no example exists for efficacy of a single product against tumors generally. Specifically, Internal Medicine, 4th Edition, Editor-in-Chief Jay Stein, Chapters 71-72, pages 699-75, teaches that the various types of cancers have different causative agents, involve different cellular mechanisms, and, consequently, differ in treatment protocol. It is also known that certain tumors are dependent upon estrogen for their induction or stimulation (such as breast tumors) and others are not. As evidenced by the Stein et al. reference, one would not expect that the instantly claimed compounds are effective in the prevention or prophylaxis of breast cancer. Therefore, based on the unpredictable nature of the invention and the state of the prior art, the lack of guidance and the extreme breadth of the claims, one skilled in the art could not use the entire scope of the claimed invention without undue experimentation.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-12 and 26-33 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Cassoni et al. Cassoni et al. teach of the administration of oxytocin or with an analog of oxytocin to inhibit breast cancer growth, (see entire article).

8. Claims 13-25 and 34-38 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Boer et al. Boer et al. teach of utilzing oxytocin to treat the psychiatric disease of obsessive compulsive disorder, (see abstract).

9. Claims 13-25 and 34-38 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Leckman et al. Leckman et al. disclose of the administration oxytocin to treat the psychiatric disease of obsessive compulsive disorder, (see abstract).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. Claims 1-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cassoni et al. in view of Lipton et al. Cassoni et al. teach of the administration of oxytocin or with an analog of

oxytocin to inhibit breast cancer growth, (see entire article). Lipton et al. disclose of the administration of tamoxifen or oestradiol to treat breast cancer. It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. . . .[T]he idea of combining them flows logically from their having been individually taught in the prior art." see *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). Accordingly, it would have been obvious to one having ordinary skill in the art to simply combine these two prior art references since both compounds are already known to treat the same ailment, specifically breast cancer. In addition, the determination of a mode of administration, such as intranasally, is well within the level of one having ordinary skill in the art, and the artisan would be motivated to determine optimum modes of administration in order to get the maximum effect of the drug.

13. Claims 26-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cassoni et al. in view of Lipton et al. Cassoni et al. teach of the administration of oxytocin or with an analog of oxytocin to inhibit breast cancer growth, (see entire article). Lipton et al. disclose of the administration of tamoxifen or oestradiol to treat breast cancer. It is obvious to combine known substances in order to generate a new composition that is known to treat the very same ailment, see *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). In addition, the selection of a known material based on its suitability for its intended use supported a prima facie obviousness determination in Sinclair & Carroll Co. V. Interchemical Corp., 325 U.S. 327, 65 USPQ 297 (1945).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. C. Jones whose telephone number is (703) 308-4634. The examiner can normally be reached on Mondays through Fridays from 8:30 am to 6:00 pm. The examiner can also be reached on alternate Mondays.

. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

DWAYNE C. JONES
PRIMARY EXAMINER
Tech. Ctr. 1614

December 12, 2001